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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/738,423	12/16/2003	Ivan C. King	873-Z-US	8783

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EXAMINER	
LI, QIAN JANICE	
ART UNIT	**PAPER NUMBER**
1633	

DATE MAILED: 12/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/738,423	KING, IVAN C.	
	Examiner	Art Unit	
	Q. Janice Li, M.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *100,103,106,108,111 and 112* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *100,103,106,108,111 and 112* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment and remarks filed 10/4/2006 have been entered. Claims 101, 102, 104, 105, 107, 109, 110 have been canceled. Claims 100, 103, 106 108, 111, 112 are pending and under current examination.

Inventorship

In view of the papers filed 10/10/2006, it has been found that this nonprovisional application, as filed, through error and without deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 CFR 1.48(a). The inventorship of this application has been changed by addition of Li-Mou Zhang.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of Office records to reflect the inventorship as corrected.

Priority

In the Remarks, applicant points to working example 28 of the priority document, U.S. patent 6,962,696, as support of instant claims. Thus, the priority for instantly claimed subject matter is now granted to the filing date of US patent application 09/645,415, i.e. 8/24/2000.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 100, 103, 106, 108, 111, 112 stand and newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are vague and indefinite because of the claim limitation, "attenuated tumor-targeting" bacteria. The specification fails to define what structure is required for a bacterium to possess that would meet claim limitation, particularly for the term "tumor-targeting", and thus the metes and bounds of the claims are unclear.

In the remarks, applicants point to page 20 or 22 of the specification for support.

In response, it is noted page 20 of the specification defines the meaning of "attenuation", does not address the structure of "tumor targeting". Page 22 of the specification reads, "tumor-targeted is defined as the ability to preferentially localize to a cancerous target cell or tissue relative to a non-cancerous counterpart cell or tissue and replicate". This passage does not make clear what structure would make a bacteria having the ability of tumor-targeting. Thus, it is still unclear what bacteria the claims encompass.

The amended claims recite "toxic LPS", it is unclear what is the structure of the toxic LPS, and thus the metes and bounds of the claims are uncertain.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 100, 103, 106, 111, 112 stand and newly rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for inhibiting the growth of a solid tumor cancer comprising administering to a subject in need an effective amount of one or more chemotherapeutic agents, supplemented with a msbB$^-$ *Salmonella* mutant (having genetically modified bacterial lipid A), does not reasonably provide enablement for inhibiting the growth of a solid tumor cancer supplemented with the genus of attenuated tumor-targeted bacteria; for reasons of record and following.

In the remarks, the applicant indicates that claims have been amended to conform to Examiner's comments.

In response, the instant amendment does not exactly address the rejected subject matter or conform to the comments in the previous Office action. Thus, for reasons of record, the rejection stands.

Further, the amended claims recite "lacking the ability to produce toxic lipopolysccharide". However, the specification fails to provide an enabling disclosure to support the full scope of the claims. Although the specification cited numerous prior art teaching that modification on lipid A pathway may reduce the ability of *E coli* bacteria to stimulate production of TNF-α (Specification, § 2.9), and thus reduce toxic effect to the host, the msbB$^-$ *Salmonella* mutant is the only bacterium taught in the specification to lack the ability to produce LPS. The skilled artisan intending to practice the invention would have required to carry out undue experimentation to find out for themselves what the genus of bacteria encompassed by the claims, and what means would make the

genus of bacteria lacking the ability to produce toxic LPS. Hence, the specification fails to provide an enabling disclosure for what is now claimed.

Therefore, in view of the limited guidance, the lack of predictability of the art and the breadth of the claims, one skill in the art could not practice the invention commensurate with the scope of the claims without undue experimentation.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 100, 103, 106, 108, 111, 112 stand rejected under 35 U.S.C. 103(a) as being unpatentable over *Low et al* (Nat Biotech 1999;17:37-41, IDS), in view of *Schachter et al* (Cancer Biother Radiopharm 1998 Jun;13:155-64).

In the remarks, applicant asserts, "Although the cytokines involved are not identical, it appears that the in vivo conditions that Schachter teaches as being required

for effective therapy would be detrimental to the approach of employing the attenuated bacterial vectors of the claimed method.

In response, it is unclear the logic behind applicant's conclusion. The Office cited *Schachter et al* to show the need and motivation was present in the art to combine chemotherapy with bio-therapy, one could use either the cytokine biotherapy as taught by *Schachter et al,* or the attenuated *Salmonella* biotherapy as taught by *Low et al* with a reasonable expectation of success for treating cancer. It was within the levels of the skilled in the art, and a matter of optimization to determine the proper dosing regimen so that the combined therapy would not lead to a detrimental effect.

The instant situation is amenable to the type of analysis set forth in In re Kerkhoven, 205 USPQ 1069 (CCPA 1980) wherein the court held that it is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose in order to produce a third composition that is to be used for the very same purpose since the idea of combining them flows logically from their having been individually taught in the prior art. Given the teaching of the prior art compositions of the attenuated tumor-targeting mutant Salmonella and chemotherapy-all taught to be useful for the treatment of cancer, it would have been *prima facie* obvious to one of ordinary skill in the art to combine these compositions to generate a new composition for the treatment of cancer with a reasonable expectation of success.

Accordingly, for reasons of record and set forth *supra*, the rejection stands.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Q. Janice Li** whose telephone number is **571-272-0730**. The examiner can normally be reached on 9:30 am - 7 p.m., Monday through Friday, except every other Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph Woitach** can be reached on **571-272-0739**. The **fax** numbers for the organization where this application or proceeding is assigned are **571-273-8300**.

Any inquiry of formal matters can be directed to the patent analyst, **William Phillips**, whose telephone number is (571) 272-0548.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is **(866) 217-9197**. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at **800-786-9199**.

Q. JANICE LI, M.D.
PRIMARY EXAMINER

Q. Janice Li, M.D.
Primary Examiner
Art Unit 1633

QJL
December 7, 2006